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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/423,018	10/12/2000	Philip Gotwals	A018	6239

7590 04/20/2004

Biogen Inc
14 Cambridge Center
Cambridge, MA 02142

EXAMINER

ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/423,018

Applicant(s)

GOTWALS ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 February 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5,8,9 and 11-29 is/are pending in the application.
- 4a) Of the above claim(s) 8,9 and 11-21 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 is/are allowed.
- 6) ☒ Claim(s) 22-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 2 February 2004 is acknowledged. Claims 5, 8, 9, and 11-29 are pending in this application. Claims 8, 9, and 11-21 are withdrawn from consideration as being drawn to a non-elected invention. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejection of claim 29 under 35 U.S.C. 103(a) as unpatentable over *Lin* in view of *Jacobs* is withdrawn. This claim recites instant SEQ ID NO: 8, which is a rabbit sequence not disclosed by *Lin*. It was erroneously included in the rejection under 103(a) of record in the office action of 17 October 2003.

Claim Rejections Maintained/New Grounds of Objection

3. The specification is newly object to because there appears to be typographical error on p. 25, line 2.

4. The rejection of claims 22-25 and 27-29 under 35 U.S.C. 112, first paragraph, as lacking enablement commensurate with the scope of the claims is maintained for reasons of record in the office action of 17 October 2003.

Applicant has amended the claims to require that the proteins encompass only biologically active regions of the proteins, or 90% homologues thereof, or equivalents thereof.

Applicant's amendment is insufficient to overcome the rejection. While one of skill in the art could make and use proteins of 90% homology with the disclosed sequences, one of skill could not predictably use proteins described as "equivalents", which are, as stated previously, of undefined homology to the disclosed sequences. As written, what is required is that the claimed

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molecule be “equivalent” to sequences of 90% homology to the disclosed sequence and that they be biologically active. Applicant has not described the properties of these proteins that are required for binding and biological function; thus one of skill in the art could not predictably identify proteins that were “equivalent” to them.

5. The rejection of claims 22-25 and 27-29 under 35 U.S.C. 112, first paragraph, as lacking written description is maintained for reasons of record in the office action of 17 October 2003.

Applicant’s amendment is not sufficient to overcome this rejection. As stated above with respect to the rejection of the claims as lacking enablement commensurate in scope with what is claimed, the claims still encompass “equivalents” of sequences of 90% homology to what is disclosed. Applicant has not described the required structural and functional characteristics of the disclosed sequences so that one of skill in the art could identify “equivalent” structures. Thus the subject matter is not described in such a way as to convey to one skilled in the art that Applicant was in possession of the invention as broadly claimed.

6. The rejection of claims 22-26 and 28 under 35 U.S.C. 103(a) is maintained for reasons of record in the office action of 17 October 2003.

Applicant argues that the rejection of the claims as lacking enablement is inconsistent with the position that the teachings of Jacobs would have led one of skill to modify Lin, because the results would have been unpredictable. Applicant further argues that Jacobs is prior art to Lin, yet Lin did not disclose the fusion proteins. Applicant concludes that no showing of a clear and particular suggestion to combine the two references has been provided.

Applicant’s arguments have been fully considered but have not been found to be persuasive.

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The two rejections are not inconsistent. The claims were rejected as lacking enablement commensurate in scope with the claims because the skilled artisan could not predictably make equivalents with the same properties of the disclosed proteins. The claimed fusion proteins, however, are combinations of two proteins with known structures and properties, a receptor and an immunoglobulin. To take a known protein with known properties and fuse it to another known protein with known properties is not an unpredictable process. Each protein has a particular function and putting the two together will result in a combined protein with both functions. This is not the same process as making an unspecified number and type of changes in a molecule, without guidance as to what regions or structures are important for the function of the molecule. That Lin did not disclose a fusion protein further does not indicate it was not obvious to make such a protein; one cannot know what Lin's objectives were, what was done and not disclosed, or what was considered too obvious to disclose. That not every obvious modification is not exemplified somewhere in the art does not render such modifications non-obvious; were they required to be exemplified, all art rejections would be made under 35 U.S.C. 102.

CLAIM 5 IS ALLOWED. CLAIMS 22-29 ARE REJECTED.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.
8 April 2004


JANET ANDRES
PATENT EXAMINER